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10/006,400	11/30/2001	Richard S. Ginn	16497.8.3.2.1	4276

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EXAMINER	
DORNBUSCH, DIANNE	
ART UNIT	**PAPER NUMBER**
3773	

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01/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,400	GINN, RICHARD S.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16,21-25,27-32,38-42,46-51,54-56,60-75 and 81-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16,21-25,27-32,38-42,46-51,54-56,60-75 and 81-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 61-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 61 recites the limitation "the deployment step" in the last line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 11-16, 21-25, 27-32, 38-42, 46-49, 51, 54-56, 60-75, and 81-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. (5,853,421) in view of Ginn, et al. (6,626,918), or Ginn, et al. (6,391,048).

For the Leschinsky reference, the examiner would like to note that reference to two embodiments are made in the rejection where the first embodiment is shown in Fig. 1-27 and the second embodiment is in Fig. 28-37. In addition, with respect to the figures of the delivery of the device (Fig. 4-24) the examiner would like to note that the same mechanisms such as parts 58, 66, 68, etc. are used with both embodiments.

6. Regarding the apparatus claims:

Claims 11, 12, 16, 21, 22, 63, 67, 85, and 89:

Leschinsky discloses an apparatus for positioning a closure device within a passage, comprising: an elongate member (combination of components 66 and 54) comprising a proximal end, a distal end, and a lumen extending between the proximal and distal ends defining a longitudinal axis (Fig. 1-13); a closure element (68) deliverable from the elongate member (combination of components 66 and 54) for sealing the passage (Fig. 16-18); and a selectively expandable locator member (14, 214), extending through the lumen (Fig. 14-16 and 28 where the embodiment of Fig. 28 is delivered in the same manner as the one seen in Fig. 14-16), the locator member (14, 214) comprising a distal portion (22 which extends from the loop (24) formed by the locator member, Fig. 28-37) extending distally beyond the distal end of the elongate member (combination of components 66 and 54) (Fig. 14-16), the distal portion comprising an elongate deflectable element (the distal portion deflects to form a J-shape end (16) as well as a loop (24) at the distal end, for the embodiment of Fig. 28-37 there is the same deflectable element but it is not shown in the drawings as disclosed in Col. 10 Line 62) comprising a helically wound wire (14, 214 is a helical wound wire as disclosed in Col. 5 Line 16 and Col. 10 Lines 59-60) extending between a proximal end and a distal end, and having an intermediate portion therebetween (Fig. 1-3, 5, and 28-29), and a control element (12 for the first embodiment, for the 2nd embodiment there are more than one control member which are 212, 228, 238) coupled to the deflectable element extending along an outer surface of at least one coil of the helical wound wire

(for the first embodiment part 12 extends along an outer surface of one coil as seen in Fig. 2 and 12, for the second embodiment the part 228 extends outward as seen in Fig. 28) and passing through at least one coil of the helical wound wire in a pre-deployed configuration (Fig. 1-3, 5, 12, 28-29 where the control element is inside the helical wound coil and the control element is connected to the distal end of the deflectable member as seen in the figures as well as the portion that extends outward as previously explained), the control element being movable axially for causing an intermediate portion of the deflectable element to buckle substantially transversely with respect to the longitudinal axis (Fig. 1-3 and 28-29 where the deflectable element forms a loop (24)) (Col. 11 Lines 45-47).

Furthermore Leschinsky discloses that the control element (12, 212, 228, 238) comprises a tether (the control element is a tether) extending along an outer surface of at least the intermediate portion of the helically wound wire in a pre-deployed configuration (Fig. 2, 12, and 28 as explained above with the part that extends outward); a housing (73, 58) slidably coupled to the elongate member (combination of components 66 and 54) (Fig. 11-13), the housing configured for releasably holding a closure element (68) (the housing is holding the closure element inside the elongated member in order to prevent it from being deployed accidentally, Fig. 10 where the closure element is being held inside the elongated member which is inside the housing 58); that at least a portion of the helically wound wire communicates with the body lumen when the helically wound wire is in the transversely expanded configuration (Fig. 6-7).

Leschinsky discloses the claimed invetion disclosed above with the exception of the closure element being a clip instead of it being a fluid sealant. However, each of the other cited references disclose the use of clips to close vascular punctures, and the two Ginn references disclose that it was known to either supplement a clip closure with a sealant, or that a clip is a known alternative to the use of a sealant in closing vessel puncture wounds. Therefore, it would have been obvious to have either exchanged the closure sealant with a clip applying device as is taught by the cited teaching references, or to add a clip applying device in combination with the sealant, as this has been shown to be an effective alternative to sealant alone in the sealing of vessel puncture wounds.

Claims 13 and 64: Leschinsky discloses a deflectable element which forms in the same manner as the deflectable element of the applicant therefore if the applicant deflectable element at the intermediate portion has a cross-section in its buckled configuration that is larger than a cross-section of the distal portion, Leschinsky's deflectable element would have the same structure.

Claims 14 and 65: Leschinsky discloses that the apparatus further comprising an actuator (244) on a proximal end of the elongate member (Fig. 15 and 29, where the actuator is at the proximal end of the locator member (Fig. 29) which in use extends through the elongated member (Fig. 15 where element 10 is the assembly of one of the embodiments which include the locator element)), the actuator (244) coupled to the locator member (14, 214) (Fig. 29), the actuator configured for moving the control element (12, 212, 228, 238) proximally for buckling the intermediate portion of the deflectable element (Col. 11 Lines 45-47). The force is applied by the operator at the

proximal end of the device where the actuator (244) is located and by bucking the control element is moved proximally.

Claims 15, 23, and 66: Leschinsky discloses that the elongate member (combination of components 66 and 54) and the selectively expandable locator member (14, 214) comprise cooperating detents (the loop (24) forms a detent at the distal end which does not allow that the locator member passes from a certain location through the lumen (second detent) of the expandable member) for substantially securing the selectively expandable locator member axially with respect to the elongate member when the selectively expandable locator member is fully inserted into the elongate member.

Claim 24: Leschinsky discloses that the apparatus further comprising an actuator (74) coupled to the housing (72) (Fig. 11-13), the actuator configured for advancing the housing distally to deploy a closure element therefrom (Col. 7 Lines (10-15). As the actuator (74) is pushed the housing is inserted closer to component 58 which allows for the closure element to be released.

Claim 25: Leschinsky discloses that the apparatus further comprising a closure element (68) located within the housing (58) (Fig. 10 where the closure element is being held inside the elongated member which is inside the housing 58).

7. Regarding the method claims:

For the apparatus limitations, please refer to the rejection above, where certain components are explained in a better manner regarding the two embodiments.

Claims 27- 29, 32, 38-40, 46, 47, 51, 54, 56, 60, 68-70, 73, 81-84, 86-88, and 90:

Leschinsky discloses a method for sealing a passage communicating with a body lumen using an elongate member (combination of components 66 and 54) comprising proximal and distal ends, and a closure element (68) deployable from the distal end of the elongate member (Fig. 16-18), the method comprising: providing a selectively expandable locator member (14, 214) coupled to the elongate member (combination of components 66 and 54) such that a distal portion 22 which extends from the loop (24) formed by the locator member) extending distally beyond the distal end of the elongate member (combination of components 66 and 54) (Fig. 14-16); advancing the distal end of the elongate member (combination of components 66 and 54) through a patient's skin towards the body lumen via the passage until the distal portion of the locator member is located within the body lumen (Fig. 14-18); moving a control element (12 for the first embodiment, for the 2nd embodiment there are more than one control member which are 212, 228, 238)) coupled to a deflectable element (the distal portion deflects to form a J-shape end (16) as well as a loop (24) at the distal end) to buckle the deflectable element on the distal portion of the selectively expandable locator member from an axial collapsed configuration to a transverse expanded configuration (Fig. 1-3, 5, and 28-29 where the deflectable element forms a loop (24)) (Col. 11 Lines 45-47), the deflectable element comprising a helically wound wire (14, 214 is a helical wound wire as disclosed in Col. 5 Line 16 and Col. 10 Lines 59-60) extending between a proximal end and a distal end and having an intermediate portion therebetween (Fig. 1-3, 5, and 28-29) and the control element (12, 212, 228, 238) extending along an outer surface of at least one coil of the helical wound wire (for the first embodiment part 12 extends along an outer

surface of one coil as seen in Fig. 2 and 12, for the second embodiment the part 228 extends outward as seen in Fig. 28) and passing through at least one coil of the helical wound wire in a pre-deployed configuration (Fig. 1-3, 5, 12, 28-29 where the control element is inside the helical wound coil and the control element is connected to the distal end of the deflectable member as seen in the figures as well as the portion that extends outward as previously explained); manipulating the elongate member until the deflectable element in the expanded configuration contacts a proximal wall of the body lumen (Fig. 5-8), thereby providing a tactile indication of a location of the distal end of the elongate member relative to the body lumen (Fig. 5-16 and Col. 6 Lines 44-49); and deploying the closure element (68) from the distal end of the elongate member (combination of components 66 and 54) within the passage (Fig. 16-18).

Additionally, Leschinsky discloses that the method further comprising withdrawing the elongate member and the selectively expandable locator member from the passage, leaving the closure element to substantially close the opening (Fig. 17-18); an introducing sheath (54) introduced into the body lumen (Fig. 7) and that more than one instrument can be introduced through the lumen of the sheath (the member (66) and the locator member (14, 214) are introduced into the lumen through the sheath as well as the dilator (56)) (Fig. 7-15); that the housing (72, 58) is movable between a proximal position (Fig. 11-13) and a distal position (Fig. 14-16), the distal position being a predetermined distance from the deflectable element in its expanded configuration (Col. 6 Lines 44-49 and Col. 7 Lines 15-18); the step of advancing a closure element

comprises advancing a housing (72, 58) along the elongate member (Fig. 10, 15, and 16) until the closure element (68) reaches the predetermined location (15-17).

Also refer to the rejections performed on the apparatus on the first part of this rejection.

Leschinsky discloses the claimed invetion disclosed above with the exception of the closure element being a clip instead of it being a fluid sealant. However, each of the other cited references disclose the use of clips to close vascular punctures, and the two Ginn references disclose that it was known to either supplement a clip closure with a sealant, or that a clip is a known alternative to the use of a sealant in closing vessel puncture wounds. Furthermore, the clip disclosed by Ginn (6,626,918) has tines (874) which penetrate the tissue when deployed.

Therefore, it would have been obvious to have either exchanged the closure sealant with a clip applying device as is taught by the cited teaching references, or to add a clip applying device in combination with the sealant, as this has been shown to be an effective alternative to sealant alone in the sealing of vessel puncture wounds.

Claims 30, 31, 71, 72: Leschinsky discloses that the body lumen comprises a blood vessel (44), and wherein the procedure comprises the delivery of a therapeutic agent (collagen is being used which is a therapeutic element).

Claim 41: Leschinsky discloses that the selectively expandable locator member (14, 214) is introduced into the lumen of the tubular member before the distal end of the tubular member (combination of components 66 and 54) is advanced into the passage such that the distal portion of the selectively expandable locator member is advanced

through the passage into the body lumen as the distal end of the tubular member is located into the passage (Fig. 5-6).

Claim 42: Leschinsky discloses that the selectively expandable locator member (14, 214) introduced into the lumen of the tubular member (combination of components 66 and 54) after the distal end of the tubular member is advanced into the passage (Fig. 10). Once the distal tip of the tubular member (54) is introduced into the passageway it is then advanced forward where the locator member is inserted into the tubular member's lumen.

Claims 48 and 49: Leschinsky discloses that the step of introducing the selectively expandable locator member comprises: disposing a tubular member (46) through a patient's skin into the passage until a distal end of the tubular member is disposed proximate the body lumen (Fig. 4); introducing the selectively expandable locator member (14, 214) into a lumen of the tubular member until the distal portion of the locator member extends beyond the distal end of the tubular member into the body lumen (Fig. 5); withdrawing the tubular member from the passage before advancing a closure element into the passage (Fig. 6-7).

Claim 55: Leschinsky discloses that the cooperating elements comprise a marker (28, 28') on the selectively expandable locator member (14, 214) (Fig. 6) having a predetermined relationship (distance D) with the distal portion of the selectively expandable locator member (Col. 5 Lines 30-33).

Claim 61: Leschinsky discloses that the deflectable element is collapsed during the deployment step (Fig. 6). The deflectable element is inserted into the lumen in a

collapsed state (the device is straight), once the deflectable member hits/attaches to the vessel wall it bends therefore the state in which it is inserted (Fig. 5) is interpreted as collapsed.

Claim 62: Leschinsky discloses that the elongate member (combination of components 66 and 54) comprises a tubular member (54), and wherein the distal portion of the selectively expandable locator member (14, 214) is retracted into the lumen after the deflectable element is collapsed (Fig16-17).

Claim 74: Leschinsky discloses that the deploying step comprises advancing a housing (58) distally along an exterior of the elongate member (66) (Fig. 10 where the housing can be moved distally along the elongated member), the housing (58) having the closure element (68) detachably held thereto (the closure element (68) is held inside the elongated member therefore one the elongated member is inside the housing so will the closure element).

Claim 75: Leschinsky discloses that the housing (58) is movable between a proximal position and a distal position (the housing can be moved distally or proximally since the device needs to be removed from the body), the distal position being a predetermined distance from the deflectable element in its expanded configuration (Col. 6 Lines 44-49 and Col. 7 Lines 15-18).

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. (5,853,421) in view of Ginn, et al. (6,626,918), or Ginn, et al. (6,391,048) in further view of Janzen (5,437,631).

Leschinsky in view of Ginn(s) teaches all the claimed limitations discussed above except for the step of introducing one or more instruments through the lumen of the tubular member into the body lumen prior to performing the closure of the blood vessel. However, Janzen discloses that introducing one or more instruments through the lumen of the tubular member (32) into the body lumen prior to performing the closure of the blood vessel (Fig. 2 and Col. 5 Lines 26-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Leschinsky in view of Ginn(s) with one or more instruments inserted into the lumen of the tubular member in view of the teachings of Janzen, since it is known in the art to use other medical devices inserted through a tubular member.

Response to Arguments

9. Applicant's arguments filed October 2, 2008 have been fully considered but they are not persuasive.

10. Applicant's arguments that Leschinsky's part 228 is not a control member is not persuasive. According to the definition of control (www.dictionary.com): an instrument or set of instruments used to operate, regulate, or guide a machine or vehicle. The part 228 is used to control that the device is not removed form the lumen of the tissue and form the body.

Additionally, the other control members made of reference in the rejection above, according to the definition of control, they are all control members since each one has a

specific part that they control in order to maintain the device in the proper location and state while the wound is sealed.

11. With respect to applicant's arguments that Leschinsky does not disclose that the control element does not extend along an outer surface of at least the intermediate portion of the helically wound wire in a pre-deployed configuration. The examiner disagrees, as seen in the rejection above, the control element in both embodiments do have a portion extending along the outer surface of at a pre-deployed configuration (Fig. 2, 12, and 28). The device is in a pre-deployed configuration since the device is deployed after the loop is made as best seen in Fig. 5.

12. With respect to applicant's arguments that Leschinsky teaches away from using a clip, the examiner disagrees since the clip can be placed in the puncture but outside of the arterial lumen. Leschinsky discloses a closure element (48) which is a plug (the plug is a foreign body which is placed inside a lumen of the body) that is placed inside the lumen of the puncture but outside the lumen of the artery.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773